

REMARKS/ARGUMENTS

The rejections presented in the Office Action dated January 22, 2007 (hereinafter Office Action) and the Advisory Action dated April 5, 2007 have been considered. Claims 1-23 and 25-66 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 7-11, 13, 18, 23, 25, 27, 48, 55-58, and 63-66 have been amended. Claim 24 has been canceled.

Support for the amendments to independent claims 1, 48, and 55 related to conductors can be found in the Specification on page 7, lines 17-19, among other locations. Support for the amendments to independent claims 1, 48, and 55 related to a pharmacological agent on a longitudinal portion of an exterior surface of a lead can be found in Fig. 4, and in the Specification on page 17, lines 25-28, among other locations. Support for the amendments to independent claims 18 and 55 related to a pharmacological agent on a portion of an exterior surface of a can may be found in Fig. 5A and in the Specification on page 13, lines 5-21, among other locations. The amendments to dependent claims 7-11, 13, 23, 25, 27, 56-58, and 63-66 carry through the amendments to independent claims 1, 18, 48, and 55, respectively. Accordingly, no new matter has been added.

Claims 1, 2, 4, 5-7, 9, 17-19, 21, 24, 32, 48, 49, 54-56, and 66 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,146,029 by *Ellinwood, Jr* (hereinafter "*Ellinwood*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Ellinwood* does not teach each and every element and limitation of amended independent claims 1, 18, 48, and 55, and therefore fails to anticipate these claims.

The Applicant's independent claims 1, 48, and 55 each recite, among other features, some variation of one or more conductors coupled to the cardiac electrode and disposed within the lead body and a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body.

Ellenwood teaches expelling stored medication from a trumpet 249 of a catheter 248. (Figs. 12, 13). The Applicant respectfully submits that *Ellenwood* does not teach that medication is provided along at least a longitudinal portion of an exterior surface of a lead body. For example, even if *Ellenwood's* "catheter 248" is construed to be a lead, wires 251 are not disposed with a lead body.

Moreover, if either of *Ellenwood's* "catheter 248" or wires 251 are construed to be a lead, *Ellenwood* expels a pharmacological agent through an inner void of a trumpet 249 and out an end of the trumpet 249. *Ellenwood* does not disclose a pharmacological agent provided along at least a longitudinal portion of the exterior surface of the catheter 248, wires 251 or trumpet 249.

Therefore, the Applicant respectfully submits that *Ellenwood* fails to teach each and every element and limitation of independent claims 1, 48, and 55.

The Applicant's independent claims 18 and 55 each recite, among other features, some variation of a pharmacological agent provided on a portion of an exterior surface of the can, wherein the can is configured to provide phoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can.

Ellenwood discloses expelling medication from a trumpet 249 of a catheter 248 as discussed previously. *Ellenwood* does not disclose a pharmacological agent provided on a portion of an exterior surface of a can.

Therefore, the Applicant respectfully submits that *Ellenwood* fails to teach each and every element and limitation of independent claims 18 and 55.

The Applicant acknowledges *Ellenwood's* mention of iontophoretic methodology in Cols. 31 and 32.

The Applicant traverses the *Examiner's* contention that phoresis merely means transportation in the context of the Applicant's claims, in light of the Applicant's

Specification and what the term phoresis would mean to one skilled in the art at the time of the Applicant's invention. The Applicant defers to the arguments made in the prior response related to interpretation of phoresis. The Applicant believes that the current amendments clearly overcome the teachings of the *Ellinwood* reference and render moot the issue of the Examiner's interpretation of the term phoresis with respect thereto.

Dependent claims 2, 4, 5-7, 9, 17, 19, 21, 24, 32, 49, 54, 56, and 66, which are dependent from independent claims 1, 18, 48, and 55, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Ellinwood*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4, 5-7, 9, 17, 19, 21, 24, 32, 49, 54, 56, and 66 are also not anticipated by *Ellinwood*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4, 5-7, 9, 17-19, 21, 24, 32, 48, 49, 54-56, and 66 as being anticipated by *Ellinwood* is not sustainable, the withdrawal of which is respectfully requested.

Claims 1, 2, 4, 5, 9, 16-19, 21, 22, 31, 32, 48, 49, 53-56, 58, 65, and 66 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,178, 349 by *Kieval* (hereinafter "*Kieval*").

The Applicant's independent claims 1, 48, and 55 each recite, among other features, some variation of one or more conductors coupled to the cardiac electrode and disposed within the lead body and a pharmacological agent provided along at least a longitudinal portion of an exterior surface of the lead body.

Kieval discloses a reservoir containing a nerve stimulating drug 122. *Kieval* states that "the reservoir 114 is operatively associated with the electrode body 112" (Col. 5, Lines 33-34) and illustrates the reservoir adjacent to an electrode body 112. *Kieval* does not teach that a pharmacological agent is provided along at least a longitudinal portion of an exterior surface of the electrode body 112 or nerve stimulator 94.

Furthermore, *Kieval* does not disclose one or more conductors coupled to a cardiac electrode and disposed within a lead body.

Therefore, the Applicant respectfully submits that *Kieval* fails to teach each and every element and limitation of independent claims 18 and 55.

The Applicant's independent claims 18 and 55 each recite, among other features, some variation of a pharmacological agent provided on a portion of an exterior surface of the can, wherein the can is configured to provide phoresis delivery of the pharmacological agent from at least the portion of the exterior surface of the can.

Kieval does not disclose a pharmacological agent provided on a portion of the exterior surface of the implantable medical device 230.

Therefore, the Applicant respectfully submits that *Kieval* fails to teach each and every element and limitation of independent claims 18 and 55.

The Applicant traverses the Examiner's contention that *Kieval's* vagus nerve stimulation constitutes electrical cardiac stimulation within the context of the Applicant's claims and Specification. The Applicant defers to the arguments made in the prior response related to electrical stimulation of the heart. The Applicant believes that the current amendments clearly overcome the teachings of the *Kieval* reference and render cardiac electrical stimulation interpretation moot with respect thereto.

Dependent claims 2, 4, 5, 9, 16, 17, 19, 21, 22, 31, 32, 49, 53, 54, 56, 58, 65, and 66, which are dependent from independent claims 1, 18, 48, and 55, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Kieval*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 4, 5, 9, 16, 17, 19, 21, 22, 31, 32, 49, 53, 54, 56, 58, 65, and 66 are also not anticipated by *Kieval*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 4, 5, 9, 16-19, 21, 22, 31, 32, 48, 49, 53-56, 58, 65, and 66 as being anticipated by *Kieval* is not sustainable, the withdrawal of which is respectfully requested.

Claims 3, 8, 10-16, 20, 23, 25-27, 29-31, 50-53, 57, and 59-65 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood*. Claims 22 and 58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood* in view of U.S. Patent No. 6,282,444 by *Kroll et al* (hereinafter "*Kroll*"). Claim 28 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Ellinwood* as applied to Claim 27 above, and further in view of U.S. Patent No. 6,295,474 by *Munshi*. Claims 3, 6-8, 10-15, 20, 23-25, 26-30, 50-52, 57, 63, and 64 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Kieval* in view of U.S. Patent No. 5,628,730 by *Shapland et al.* (hereinafter "*Shapland*"). Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Kieval* in view of U.S. Patent No. 5,749,909 by *Schroeppe* *et al.* (hereinafter "*Schroeppe*").

Each of dependent claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 depend from one of independent claims 1, 18, 48, and 55. Each of the rejections listed above use one of the *Ellinwood* or *Kieval* references to teach or suggest the elements and limitations of the independent claims, and use the other references for various elements and limitations of rejected dependent claims. With reference to the above discussions of the *Ellenwood* and *Kieval* references, the Applicant respectfully submits that *Ellenwood* and *Kieval* each respectively fails to teach or suggest each and every element and limitation of independent claims 1, 18, 48, and 55. Moreover, *Kroll*, *Munshi*, *Shapland*, and *Schroeppe* fail to properly supply the missing teachings or suggestions, even through the Office Action does not rely on these references for such purposes.

As such, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim

depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 not made obvious by *Kieval* or *Ellinwood*, even in combination with *Kroll*, *Munshi*, *Shapland*, or *Schroeppel*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 3, 6-8, 10-16, 20, 22-31, 50-53, 57, and 59-65 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, stated interpretations of the claims or cited references, capable configurations, obvious design choices, proposed advantages, stated problem solutions, performance expectations, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching or suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.626PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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